DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Martin A. Weinstock, MD, PhD
Chairman, Skin Cancer Advisory Group
Mary O'Connell
Director, Skin Cancer Initiatives
American Cancer Society
1599 Clifton Road, NE
Atlanta, Georgia 30329-4251

Dear Dr. Weinstock and Ms. O'Connell:

This is in response to your letter dated June 1, 2000, and subsequent telephone conversations with Ms. Elizabeth Yuan of our office, concerning the labeling of over-the-counter (OTC) sunscreen drug products. We apologize for the delay in responding to your letter. However, in the context of your inquiry, we believed it prudent to first ascertain the nature of the data and information that were being submitted by all interested persons in response to the recent opening of the administrative record for the rulemaking for OTC sunscreen drug products.

Your letter referenced our response dated March 8, 2000 to your letter dated February 9, 2000 in which you expressed concern that consumers may not understand how often a sunscreen needs to be reapplied to retain its effectiveness. Our response of March 8, 2000 stated, among other things, that the Food and Drug Administration (FDA) would reconsider the reapplication and/or water resistance statements in the OTC sunscreen drug products monograph pending the submission and evaluation of data necessary to substantiate additions to or modifications of these statements (as described in the preamble to the final monograph). Your letter of June 1, 2000 asked if data answering the following questions (utilizing a survey of consumers and a scientific conference, respectively) would be potentially sufficient to lead FDA to reconsider the sunscreen reapplication statement:

(1) How do people actually use sunscreens?
(2) What is the rate at which sunscreens degrade over time?

Sunscreen substantivity in the final monograph is addressed by the water resistance test described in 21 CFR 352.76 and the required labeling relative to retention of the sun protection factor (SPF) after either 40 or 80 minutes of activity in the water (and/or sweating). The Australian "standards for hours of protection" referenced in your letter of February 9, 2000 are also derived from water resistance testing as specified in their standards (in conjunction with bracketed SPF values).

The water resistance testing procedure in the sunscreen drug products final monograph limited total water immersion time to 80 minutes based upon unpublished marketing data evaluated by the FDA Advisory Review Panel on OTC Topical Analgesic, Antirheumatic,

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Otic, Burn, and Sunburn Prevention Drug Products. The data revealed that a typical population of adults and children under 12 years of age goes into the water 3.6 times for an average duration of 21 minutes per immersion at the beach or pool (an average total immersion time of approximately 80 minutes). The Panel believed the data represented a reasonable and fair representation of swimming habits.

As noted in the preamble to the OTC sunscreen drug products final rule (copy included with our March 8th response), data have already been submitted to the agency to demonstrate that some sunscreen drug products may retain their SPF values during water resistance testing in excess of the 80 minute indication allowed by the monograph. At that time, the agency also stated that it will reconsider the 80-minute limit if it receives data indicating customary usage patterns in excess of 80 minutes of total water exposure.

The agency believes that the use of sunscreen alone will not prevent all of the possible harmful effects due to the sun. Variation between individuals, ultraviolet radiation absorption and substantivity of sunscreen drug products, exposure conditions, and conditions of use cannot promise a precise result for each individual. The agency believes that consumers should be encouraged to reapply water resistant/very water resistant sunscreen drug products at minimal intervals in order to be most effective. Therefore, any usage data must also be evaluated in the context of appropriate labeling that does not provide the wrong message or a false sense of security to some consumers. Relative to the potential for extended water resistance claims, we would also be interested in receiving data and information concerning the assignment of specific water resistance time intervals to specific SPF values.

Further, as noted by a comment addressed in the preamble to the OTC sunscreen drug products final rule (copy provided with our March 8th response), some firms may have data demonstrating that their sunscreen drug products may not need to be applied as frequently at some select time period. Because the OTC sunscreen drug product monograph applies to a broad range of formulations and dosage forms, including water resistant and non-water resistant products, the agency provided a general reapplication direction in the monograph. Understanding, however, that manufacturers may have data to support reapplication instructions based upon information specific to their product, the agency also invited the submission of such information for approval via a new drug application deviation as provided in 21 CFR 330.11. Thus, the agency will also reconsider the sunscreen reapplication statement in this product-specific context.

Your second point concerned the possible photodegradation of sunscreen drug products relative to the agency's reconsideration of a reapplication statement. In response to the reopening of the administrative record for the OTC sunscreen drug products rulemaking (65 FR 36319, June 8, 2000), comments were received concerning the photostability of sunscreen drug products, including suggested testing procedures (the comments are publicly available in docket 78N-0038 at the FDA Dockets Management Branch). The agency intends to review these comments and any other new information in conjunction with its evaluation of testing methodology for both ultraviolet B (UVB) and ultraviolet A (UVA) radiation protection. Based upon published studies and other information already received in the sunscreen drug products rulemaking, we anticipate that photodegradation will be

addressed within the final formulation testing methodology to be proposed by the agency in a future issue of the Federal Register. Therefore, you may want to wait until the agency evaluates these data before the American Cancer Society conducts further research in this area.

Any data supporting a specific labeling change, testing modification, etc., to the sunscreen drug products final monograph should be submitted as a petition in accordance with 21 CFR 10.30 (referencing the sunscreen drug products rulemaking public docket 78N-0038). Information and inquiries should be submitted in triplicate to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Again, the FDA shares your views that OTC sunscreen drug products should be safe and effective and that their labeling should provide useful and understandable information concerning product use. We hope this information is helpful.

Sincerely yours,

Charles J. Ganley, MD
Director
Division of OTC Drug Evaluation
Center for Drug Evaluation and Research